K133836

Section 5 – 510(k) Summary

MAR – 6 2014

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1. Submitter Information:

GC AMERICA INC.
3737 W. 127th Street
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Contact Person: Mark Heiss, D.D.S.
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Date Prepared: December 13, 2013

2. Device Name:

Proprietary Name: Optiglaze Color
Classification Name: Coating, Filling Material, Resin
Device Classification: Class II, 872.3310
Product Code: EBD

3. Predicate Devices:

Company	Device	510(k) No.	Date Cleared
GC America Inc.	G-Coat	K052462	10/20/05

4. Description of Device:
5. Optiglaze Color is a light-cured glazing and for characterization of direct and indirect composite restorations, acrylic denture base and artificial acrylic teeth, and also for obtaining surface smoothness and wear resistance of restorations made of composite resin, acrylic denture base and artificial acrylic teeth. The material is available in 17 shades.

6. Indications for Use:
   a. For characterization of direct and indirect composite restorations, acrylic denture base and artificial acrylic teeth.
   b. For obtaining surface smoothness and wear resistance of restorations made of composite resin, acrylic denture base and artificial acrylic teeth.

7. Technological characteristics:
   All the components of the applicant device, Optiglaze Color, have already been used in the predicate devices. The curing mechanism of the predicate devices is polymerization of uncured methacrylate ester monomers. This reaction is caused by photo initiator system.

8. Substantial equivalence:
   The applicant device complies with all the requirements of ISO 10993-1 Biological evaluation of medical devices Part 1: Evaluation & testing.

   The curing mechanism of the new and predicate devices is substantially equivalent in principle. Therefore, the new and predicate devices are the same in function, and similar in composition and intended use. This supports that the compatibility and safety of the applicant device are substantially equivalent to the predicate devices.

9. Differences
The following differences may be noted between the predicate device and Optiglaze Color:
- Optiglaze Color has higher surface hardness and comes in multiple shades.

10. Performance Bench Tests
It is confirmed that the device conforms to the required specifications and is suitable for its intended use. Performance testing includes:
- Appearance
- Depth of cure
- Color stability after irradiation
- Surface hardness
- Application characteristics

9. Packaging
Complete set: A-Plus 2.6ml, B-Plus 2.6ml, C-Plus 2.6ml, White 2.6ml, Ivory-White 2.6ml, Yellow 2.6ml, Orange 2.6ml, Pink-Orange 2.6ml, Pink 2.6ml, Red-Brown 2.6ml, Olive 2.6ml, Lavender 2.6ml, Grey 2.6ml, Blue 2.6ml, Red 2.6ml, Clear 5ml, Clear HV 5ml

Accessories
Disposable Pallet
Flat Brush
Round Brush
Brush Holder
Box

10. Shelf Life Evaluation and Storage Conditions:
- Shelf Life 3 years
- Store in a cool and dark place. 4-25°C (39.2 - 77.0°F)

	Applicant device	Comparative device
Product category	Coating, Filling Material, Resin, Class II	Coating, Filling Material, Resin, Class II
Trade name	OPTIGLAZE COLOR	G-Coat
Manufacturer	GC Corporation	GC Corporation
Intended use	For characterization of restorations made of composite resins & acrylics. For obtaining surface smoothness and wear resistance of restorations made of composite resins & acrylics.	Used to seal the surface of followings to protect from moisture and dehydration, and to provide an extra smooth surface gloss: direct composite and glass-ionomer restorations, indirect composite restorations, provisional restorations, and their adhesive interface of margin to enamel or dentin.
Product description	OPTIGLAZE COLOR is a light-cured glazing and characterizing material for such restorations as direct and indirect composite resins & acrylics.	G-COAT is a light-cured protective coating agent to be used to seal the surface of such restorations as direct or indirect composites, glass-ionomer restorations, provisional and the interface between those restorations and enamel or dentine. The coated surface presents high smoothness, and it may reduce or even eliminate the need for manual polishing.

		polishing.
Components	Multifunctional acrylate. Methyl methacrylate. Silica filler (amorphous, fumed). Photo initiator. Pigment.	Multifunctional methacrylate. Methyl methacrylate. Silica filler (amorphous, fumed). Photo initiator.
Instructions for use	1) After contouring the resin surface, finish with a carbide bur or coarse silicone point. 2) Wash and dry the surface. 3) Apply a thin layer to the resin surface using the brush provided. 4) Light cure with LaboLight LV-3 or equivalent halogen light for 5 minutes.	a) Contour restoration according to the manufacturer's instructions. b) Clean the restoration and adjacent surfaces to be coated with pumice and water. c) Rinse and dry. d) Using a cotton pellet or brush apply G-COAT to all exposed restoration and adjacent surface. e) Light cure for 20 seconds using suitable visible light curing device. f) Close bottle immediately after use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

March 6, 2014

GC AMERICA INCORPORATED
Dr. Mark Heiss, D.D.S.
3737 W. 127th Street
Alsip, IL 60803

Re: K133836
Trade/Device Name: OPTIGLAZE COLOR
Regulation Number: 21 CFR 872.3310
Regulation Name: Coating Material For Resin Fillings
Regulatory Class: II
Product Code: EBD
Dated: December 13, 2013
Received: December 18, 2013

Dear Dr. Heiss:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Erin I. Keith -S

Erin I. Keith, M.S.
Acting Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 4 – Indications for Use Statement

Indications for Use

510(k) Number (if known): K133836

Device Name: Optiglaze Color

Indications for Use:

1. For characterization of direct and indirect composite restorations, acrylic denture base and artificial acrylic teeth.
2. For obtaining surface smoothness and wear resistance of restorations made of composite resin, acrylic denture base and artificial acrylic teeth.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mary S. Runner -S
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